

**Department of Defense
Human Research Protection Program**

**DEPARTMENT OF DEFENSE (DOD) ADDENDUM TO THE DEPARTMENT OF HEALTH
AND HUMAN SERVICE'S (DHHS) FEDERALWIDE ASSURANCE (FWA) FOR THE
PROTECTION OF HUMAN SUBJECTS**

General Instructions to Institutions

- This form is a tool to help Institutions with an existing FWA approved by DHHS to know about and acknowledge key DoD policies and requirements since the DHHS FWA does not identify DoD requirements.
- Contact your DoD Component Sponsor for guidance if you have questions.
- Complete and print your Addendum on your Institution's letterhead.
- Follow your DoD Component Sponsor's instructions for paper or electronic submission.
- Part 1, A. If you need to update an existing Addendum, contact your DoD Component Sponsor for guidance.
- Part 1, B. Description of the Institution: List any organizations under the jurisdiction of the Institution that are well known and describe the kinds of research areas that will be covered by this Addendum.
- Part 3. All of the DoD Components' top-level policies are listed in this section. This is so that this one Addendum can be submitted by the Institution and approved by one DoD Component on behalf of the entire DoD.
- Part 5. Complete Section A for all IRB(s) used by your Institution IF the IRB is part of your Institution. Complete Section B for all IRB(s) used by your Institution if the IRB is NOT part of your Institution. For each IRB in Section B, attach your DoD Institutional Agreement for IRB Review (or equivalent agreement) to your Addendum. All of the IRBs supporting the Institution do not need to be listed in Tables 1 and 2. List only those IRBs that will review DoD-supported research.
- Part 6. The "Official Legally Authorized to Represent the FWA Institution" is the person who signed the FWA as the Institutional Official.

**Department of Defense
Human Research Protection Program**

**DEPARTMENT OF DEFENSE (DOD) ADDENDUM TO THE DEPARTMENT OF HEALTH
AND HUMAN SERVICE'S (DHHS) FEDERALWIDE ASSURANCE (FWA) FOR THE
PROTECTION OF HUMAN SUBJECTS**

This Addendum is for non-DoD Institutions that already have an FWA approved by DHHS and will be engaged in DoD-supported human subject research.

**Part 1
INSTITUTION INFORMATION**

A. Purpose of DoD Addendum

- New
 Renewal for DoD Addendum Number:

B. Institution Information

Name:
DHHS FWA Number:
DHHS FWA Expiration Date:
Description of the Institution:

C. Scope

This Addendum applies to all DoD-supported human research protocols performed by this institution, unless specified below.

Limitation of Scope (if applicable): _____

D. Effective Date

This Addendum is effective as of the date this document is approved by the DoD Component Designated Official (CDO) and expires on the DHHS Federal Wide Assurance Expiration Date in B above. CDO approval is documented in an official memorandum.

Part 2 DOD REQUIREMENTS

In addition to the requirements identified in the Institution's FWA, this institution assures it shall comply with the following laws, regulations, and guidance when conducting, reviewing, approving, overseeing, supporting, or managing DoD-supported research with human subjects:

- Title 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects"
- Title 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects," Subparts B, C, and D as made applicable by DoDD 3216.02
- Title 21 Code of Federal Regulations 50, 56, 312, and 812, Food and Drug Administration (FDA) Regulations
- DoD Directive (DoDD) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research"
- Title 10 United States Code Section 980 (10 USC 980), "Limitation on Use of Humans as Experimental Subjects"
- DoDD 3210.7, "Research Integrity and Misconduct"
- DoD Instruction (DoDI) 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs"

Part 3 DOD COMPONENT REQUIREMENTS

The institution assures it shall also comply with DoD Component requirements for the research protocol(s) sponsored by that DoD Component. The requirements for each DoD Component are listed below. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Addendum (32 CFR 219.101(d)).

Department of the Army

- AR 70-25 Use of Volunteers as Subjects of Research, 25 January 1990
- AR 40-38, Clinical Investigation Program, 1 September 1989
- AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 4 January 1991

Department of the Navy

- SECNAVINST 3900.39D of 6 November 2006

Department of the Air Force

- Air Force Instruction 40-402, Protection of Human Subjects in Research

Office of the Under Secretary of Defense for Personnel and Readiness

- HA Policy 05-003

Part 4 INSTITUTION RESPONSIBILITIES

The complete list of requirements for compliance is provided above in Part 2, DoD Requirements; Part 3, DoD Component Requirements; and in the institution's FWA. A select list of responsibilities of the Institutional Official, IRB, and Investigators are identified below. This partial list is taken from the regulations and guidance listed in Parts 2 and 3. The institution should communicate with the DoD organization supporting the research to ensure the institution and their IRB are in compliance.

- Conduct initial and continuing research ethics education for personnel who are engaged in human subject research (e.g., who review, approve, oversee, or manage research)
- Document determination by a designated Institutional Official (other than investigators) whether research meets criteria for exemption
- Ensure new research and substantive scientific amendments to approved research shall undergo scientific review and that the review is considered by the IRB
- Ensure additional protections for military research subjects to minimize undue influence
- Explain to subjects any provisions for medical care for research-related injury
- Report unanticipated problems, adverse events, research-related injury, and suspensions or terminations of research
- Appoint a Medical Monitor when necessary
- Safeguard for research conducted with international populations
- Protect pregnant women, prisoners, and children
- Comply with DoD limitations on research where consent by legally authorized representatives is proposed
- Comply with DoD limitation on exceptions from informed consent (e.g., 10 USC 980, 45 CFR 46, and 21 CFR 50)
- Comply with limitations on dual compensation for U. S. military personnel
- Follow DoD requirements for additional review for DoD-sponsored survey research or survey research within DoD
- Address and report allegations of non-compliance with human research protections
- Address and report allegations of research misconduct
- Follow procedures for addressing financial and other conflicts of interest
- Prohibit research with prisoners of war (POW)
- Comply with all provisions for research with human subjects using investigational test articles (drugs, device, and biologics)
- Follow recordkeeping requirements
- Support oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)

Part 5

DESIGNATION OF IRB(S) THAT WILL REVIEW DOD-SUPPORTED RESEARCH

All of the IRBs supporting the institution do not need to be listed in Tables 1 and 2. List only those IRBs that will review DoD-supported research.

A. IRB(s) that are Part of this Institution

In Table 1, identify each IRB that is organizationally part of this institution and can review DoD-supported research under this Addendum to the FWA (the IRBs should also be listed on the FWA). For each IRB listed in Table 1, the IRB Chair must sign this Addendum in Part 6. When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 1. IRB(s) within the Institution

IRB Name or Number	DHHS IRB Registration Number (8 digits)
1.	
2.	
3.	
4.	

B. IRB(s) that are not Part of this Institution

In Table 2, identify each IRB that is not associated with this institution and can review DoD-supported research under this Addendum to the FWA. For each IRB listed in Table 2, attach the DoD Institutional Agreement for IRB Review (or an equivalent agreement). When requested by the DoD-sponsor, attach the membership list for each IRB listed (in accordance with 45 CFR 46); see Table 3 for an example.

Table 2. IRB(s) not part of this Institution

IRB Name or Number	DHHS IRB Registration Number (8 digits)*	Name of the Institution Providing the IRB	DoD Assurance Number of the Institution*	DHHS FWA Number of the Institution*
1.				
2.				
3.				
4.				
5.				
6.				

* If applicable.

Part 6

INSTITUTIONAL AGREEMENT

A. Official Legally Authorized to Represent the FWA Institution (i.e., signed the FWA)

Acting in an authorized capacity on behalf of this institution and with an understanding of the institution's responsibilities under its FWA and this Addendum, I assure protections for human subjects as specified above.

Signature:

Date:

Name:

Institutional Title:

Mailing Address:

Telephone number:

Email address:

B. Chair(s) of the IRB(s) that are part of the Institution and listed in Table 1

Acting in an authorized capacity on behalf of this institution's IRB(s) and with an understanding of the IRB's responsibilities under the institution's FWA and this Addendum, I assure protections for human subjects as specified above.

Signature:

Date:

Name:

Institutional Title:

Name(s) or Number of IRB:

Mailing Address (if different from the Institutional Official above):

Telephone number:

Email address:

Note: If there are multiple IRBs listed in Table 1, each Chair should sign this Addendum and provide the information in this section. If a Chair presides over multiple IRBs listed in Table 1, provide the name and number of each IRB in this section.

C. Primary Contact - Human Research Protection of the FWA Institution

Name:

Institutional Title:

Mailing Address (if different from the Institutional Official above):

Telephone number:

Email address: